



Fact Sheet: Announcement of Preliminary Regulatory Determinations for Priority Contaminants on the Drinking Water Contaminant Candidate List

1. What is the Contaminant Candidate List?

The Safe Drinking Water Act (SDWA), as amended in 1996, requires EPA to publish a list of contaminants (referred to as the Contaminant Candidate List, or CCL) to assist in priority-setting efforts. SDWA also requires the Agency to select five or more contaminants from the current CCL and determine, by August 2001, whether or not to regulate these contaminants with a National Primary Drinking Water Regulation (NPDWR).

The CCL was developed with considerable input from the scientific community and stakeholders. A draft CCL requesting public comment was published in October of 1997 and a final in March of 1998. The CCL contains 60 contaminants (50 chemicals and 10 microbes) that are not subject to any current or proposed NPDWRs.

2. What contaminants are EPA considering for regulation?

In 1998, 20 of the 60 contaminants were classified as priorities for regulatory determination because it was believed at that time that there were sufficient data to evaluate both exposure and risk to public health, and to support a determination of whether or not to proceed to promulgation of an NPDWR.

Since then, 12 of the 20 priority contaminants were found to have insufficient information to support a regulatory determination. In addition, sodium was added to the list of regulatory determination priorities.

Below are the 9 contaminants that have sufficient data and information to consider for a determination of whether or not to regulate. Please see the appendix for summary information on each contaminant.

- *Acanthamoeba* – microscopic amoeba commonly found in the environment
- Aldrin – banned insecticides, used primarily on corn and cotton
- Dieldrin – banned insecticides, used primarily on corn and cotton
- Hexachlorobutadiene – used primarily to make rubber compounds
- Manganese – essential nutrient, occurs naturally, and has a variety of uses
- Metribuzin – herbicide used primarily on soybeans, potatoes, and alfalfa
- Naphthalene – intermediary manufacturing product and moth repellent
- Sodium – essential nutrient, naturally occurring element
- Sulfate – present in the diet, naturally occurring element

3. What did EPA decide and what happens next?

Our preliminary determination is that regulatory action is not appropriate or necessary for any of the nine contaminants. After a 60 day comment period and stakeholders meeting, EPA will publish the final determinations in late 2002. Should the Agency determine that regulations are necessary, they must be proposed in late 2004, and promulgated by the summer of 2005.

4. What analyses did EPA undertake to make this decision?

When making a determination to regulate, SDWA requires consideration of three areas: projected adverse health effects, extent of contaminant occurrence, and whether regulation would present a meaningful opportunity for health risk reduction (see SDWA §1412(b)(1)(A)).

EPA developed the evaluation approach based on recommendations from National Research Council (NRC) and the National Drinking Water Advisory Council (NDWAC, one of the formal means that we work with stakeholders on drinking water issues). For each of the nine contaminants, EPA evaluated the sufficiency of current analytical and treatment methods; the best available peer reviewed data on health effects; and up to approximately seven million analytical records on contaminant occurrence. For those contaminants with adequate methods, as well as health effects and occurrence data, EPA employed an approach to assist in making preliminary regulatory determinations that follows the themes recommended by the NRC and NDWAC to satisfy the three SDWA requirements under section 1412(b)(1)(A)(i)-(iii). The process was independent of many of the more detailed and comprehensive risk management factors that will influence the ultimate regulatory decision making process. Thus, a decision to regulate is the beginning of the Agency regulatory development process, not the end.

Specifically, EPA characterized the human health effects that may result from exposure to a contaminant found in drinking water. Based on this characterization, EPA estimated a health-related bench-mark level for each contaminant. Then, for a given contaminant EPA estimated the number of public water systems and population served by those systems above these bench-mark values, and the geographic distribution using a large number of state occurrence data that broadly reflect national coverage. Use and environmental release information, and ambient water quality data, were used to augment the State data and evaluate the likelihood of contaminant occurrence.

The findings from these evaluations were used to make a preliminary determination on whether to regulate a contaminant based on the three SDWA statutory requirements. The findings of these evaluations are summarized in the appendix.

In addition, EPA has asked the Science Advisory Board to review the supporting data and analysis, the approach used for making regulatory determinations, and the preliminary regulatory determinations.

5. Additional Considerations

EPA is only making regulatory determinations on CCL contaminants that have sufficient information to support a regulatory determination at this time. The Agency continues to conduct research and/or to collect occurrence information on the remaining CCL contaminants. EPA has been aggressively conducting research to fill identified data gaps and recognizes that stakeholders may have a particular interest in the timing of future regulatory determinations for other contaminants on the CCL. Stakeholders may be concerned that regulatory determinations for such contaminants should not necessarily wait until the end of the next regulatory determination cycle.

In this regard, it is important to recognize that the Agency is not precluded from monitoring, conducting research, developing guidance, or regulating contaminants not included on the CCL to address an urgent threat to public health (see SDWA section 1412(b)(1)(D)); or taking action on CCL contaminants when information becomes available. The Agency continues to conduct research and/or to collect occurrence information for contaminants on the CCL (except the nine for which preliminary determinations are being made) and may proceed with regulatory determination prior to the end of the next regulatory determination cycle.

We are soliciting comment on which of the remaining CCL contaminants stakeholders believe should have the highest priority for future regulatory determinations and their reasons in support of such comments.

6. Where can I find more information about this notice and the CCL?

For general information on the CCL, please visit the EPA Safewater Web site at <http://www.epa.gov/safewater> or contact the Safe Drinking Water Hotline at 1-800-426-4791. The Safe Drinking Water Hotline is open Monday through Friday, excluding Federal holidays, from 9:00 a.m. to 5:30 p.m. Eastern Time. In addition to this fact sheet, the following documents are electronically available to the public at EPA's web site on the CCL:

- (A) The *Federal Register* announcing the preliminary regulatory determinations for priority contaminants on the CCL; and
- (B) The technical support documents for the CCL Regulatory Determinations *Federal Register*:
 - ▶ Analysis of National Occurrence of the 1998 Contaminant Candidate List (CCL) Regulatory Determination Priority Contaminants in Public Water Systems.
 - ▶ Health Effects Support Document for *Acanthamoeba*
 - ▶ Health Effect Support Document for Aldrin and Dieldrin
 - ▶ Regulatory Determination Support Document for Aldrin and Dieldrin
 - ▶ Health Effects Support Document for Hexachlorobutadiene

- ▶ Regulatory Determination Support Document for Hexachlorobutadiene
- ▶ Health Effects Support Document for Manganese
- ▶ Regulatory Determination Support Document for Manganese
- ▶ Health Effect Support Document for Metribuzin
- ▶ Regulatory Determination Support Document for Metribuzin
- ▶ Health Effect Support Document for Naphthalene
- ▶ Regulatory Determination Support Document for Naphthalene
- ▶ Draft Drinking Water Advisory: Consumer Acceptability Advice and Health Effects Analysis on Sodium
- ▶ Regulatory Determination Support Document for Sodium
- ▶ Draft Drinking Water Advisory: Consumer Acceptability Advice and Health Effects Analysis on Sulfate
- ▶ Regulatory Determination Support Document for Sulfate

For a hard copy of this fact sheet (EPA 815-F-02-003), the *Federal Register* notice, and/or any of the supporting documents for the CCL Regulatory Determinations notice, please contact EPA's Water Resource Center at 1-800-832-7828.

Appendix

CCL Regulatory Determination Information Sheet *Acanthamoeba*

Background

- ▶ *Acanthamoeba* are microscopic amoeba commonly found in the environment.

Adverse health effects

- ▶ Several species have been found to infect humans. The two major disease conditions are keratitis and granulomatous amoebic encephalitis (GAE).
 - *Acanthamoeba* keratitis. Keratitis, or corneal infection, occurs when amoebas enter the eye via contact lenses or through a cut in the cornea. Infection occurs predominantly in individuals who wear soft contact lenses and is thought to be a consequence of improper storage, handling, and disinfection of the lenses or lense case; wearing lenses in hot tubs and during swimming; and the formation of bacterial biofilms on contact lenses and lens storage cases. *Acanthamoeba keratitis is not known to be produced by ingestion of drinking water, inhalation during showering, or other standard uses of drinking water.*
 - GAE. Occurs mostly in chronically ill individuals with compromised immune systems. Routes of entry are the respiratory tract and skin lesions.

Occurrence and exposure

- ▶ *Acanthamoeba* are found worldwide in a wide range of environmental media, *it is assumed* that finished drinking water may be source of exposure, however, PWSs do not monitor for *Acanthamoeba*.
- ▶ Between 1973 and 1996 an estimated 700 *Acanthamoeba* keratitis cases occurred in the U.S. There appears to be an increased incidence in keratitis over the past decade that may be attributed to the increase in the number of contact lens wearers.
- ▶ GAE is not a reportable disease in the U.S.; however, about 110 cases of GAE have been reported world-wide; 64 cases have been reported in the U.S., of which 30 cases were diagnosed in AIDS patients. Reports indicate that the possible routes of entry of *Acanthamoeba* in individuals are through the respiratory tract and from skin lesions. Thus, it is unlikely that any of the cases were associated with ingestion of *Acanthamoeba* in drinking water.

Preliminary regulatory determination

- ▶ The Agency has made the preliminary determination not to regulate *Acanthamoeba* with a NPDWR since regulation would not present a meaningful opportunity for health risk for the people served by public drinking water systems. Several species of *Acanthamoeba* infect humans and can be found worldwide in a range of environmental media (*e.g.*, soil, dust, and fresh water). Because of this, it is assumed that finished drinking water may be source of exposure. However, *Acanthamoeba* keratitis is not known to be produced by ingestion of drinking water, inhalation

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during showering, or other standard uses of drinking water. Rather, keratitis is associated with poor hygiene practices among contact lens wearers. GAE has been reported in a very small number of individuals known to be at risk for developing this disease; there have been a total of 64 U.S. cases which is a low incidence even considering the possible vulnerability of an estimated number of immunocompromised and diabetic individuals of 10 million. It is unlikely that any of the cases were associated with ingestion of *Acanthamoeba* in drinking water.

- ▶ An effective means to protect public health is to identify those groups of individuals who may be at risk or more sensitive than the general population to the harmful effects of *Acanthamoeba* in drinking water and target them with protective measures (*e.g.*, encourage contact lens wearers to follow manufacturers' or health care practitioners' instructions for cleaning and rinsing their contact lens). EPA intends to release a guidance document addressing the risks of *Acanthamoeba* infection.

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CCL Regulatory Determination Information Sheet *Aldrin and Dieldrin*

Background

- ▶ Aldrin and dieldrin are the common names of two structurally similar insecticides. They are discussed together because aldrin readily changes to dieldrin in the body and in the environment, and they cause similar adverse health effects.
- ▶ Popular pesticides for corn and cotton from 1950-1970.
- ▶ Banned in 1974 except to control termites, banned for all uses in 1987.
- ▶ EPA issued health advisories in 1992 (aldrin) and 1988 (dieldrin).

Adverse health effects

- ▶ Both are classified as, “likely to be carcinogenic to humans.”
- ▶ EPA used only the best available peer reviewed data and analyses to characterize health effects. Based on this characterization, the Agency estimated a health-related benchmark, or Health Reference Level¹ (HRL = 0.002 $\mu\text{g/L}$ for both aldrin and dieldrin), against which to evaluate the occurrence data.

Occurrence and exposure

- ▶ For the most part, exposure occurs when people eat contaminated foods.
- ▶ Aldrin and dieldrin were monitored under the Agency’s Unregulated Contaminant Monitoring program² from 1993-1999.
- ▶ EPA estimated the number of PWSs with detections $>1/2\text{HRL}$ and $>\text{HRL}$; the population served at these bench-mark values; and the geographic distribution using a large number of State occurrence data that broadly reflect national coverage.
 - Aldrin detections $>1/2\text{HRL}$ and $>\text{HRL}$. 0.02% of the reporting PWSs (2 out of 12,165) experienced detections of aldrin at $>1/2\text{HRL}$, and $>\text{HRL}$ affecting 0.02% of the population served (8,600 out of 47.8 million people).
 - Dieldrin detections $>1/2\text{HRL}$ and $>\text{HRL}$. 0.09% of the reporting PWSs (11 out of 11,788) have detections of dieldrin at $>1/2\text{HRL}$, and $>\text{HRL}$ 0.07% of the population served (32,000 out of 45.8 million).

Preliminary regulatory determination

- The Agency has made the preliminary determination not to regulate aldrin or dieldrin with a NPDWR since regulation would not present a meaningful opportunity for health risk for the people served by public drinking water systems. EPA recognizes that aldrin and dieldrin are probable human carcinogens, but the chemicals have been banned for most uses since 1974, and have relatively low levels of occurrence in drinking water supplies. It is likely that there will be so few people exposed to aldrin and dieldrin in their drinking water that a national regulation to

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control these two pesticides may not be significant in reducing cancer risk.

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CCL Regulatory Determination Information Sheet *Hexachlorobutadiene*

Background

- Used to make rubber compounds, also used as a solvent.

Adverse health effects

- Classified as, “likely to be a carcinogen to humans.”
- EPA used only the best available peer reviewed data and analyses to characterize health effects. Based on this characterization, the Agency estimated a health-related benchmark, or Health Reference Level¹ (HRL = 1 $\mu\text{g/L}$), against which to evaluate the occurrence data.

Occurrence and exposure

- Most exposure to hexachlorobutadiene comes from breathing it in workplace air. People living near hazardous waste sites containing hexachlorobutadiene may be exposed to it by breathing air or by drinking contaminated water.
- Hexachlorobutadiene was monitored under the Agency’s Unregulated Contaminant Monitoring program² from 1988-1992 (“Round 1”) and 1993-1999 (“Round 2”).
- EPA estimated the number of PWSs with detections $>\frac{1}{2}\text{HRL}$ and $>\text{HRL}$; the population served at these bench-mark values; and the geographic distribution using a large number of State occurrence data that broadly reflect national coverage.
 - Round 1 detections $>\frac{1}{2}\text{HRL}$ and $>\text{HRL}$. 0.16% of the reporting PWSs (20 out of 12,284) had detections $>\frac{1}{2}\text{HRL}$, affecting 0.57% of the population served (407,000 out of 71.6 million). The percentage of reporting PWSs with detections $>\text{HRL}$ is 0.11% (14 out of 12,284), affecting 0.37% of the population served (263,000 out of 71.6 million).
 - Round 2 detections $>\frac{1}{2}\text{HRL}$ and $>\text{HRL}$. 0.08% of the reporting PWSs $>\frac{1}{2}\text{HRL}$ (18 out of 22,736), affecting 2.3% of the population served (1.6 out of 67 million). The percentage of the reporting PWSs with detections $>\text{HRL}$ is 0.02% (4 out of 22,736), affecting 0.005% of the population served (3,350 out of 67 million).
- Qualifying statement
 - Round 1 monitoring results are influenced by the State of Florida, which may have incomplete and problematic data that may inflate the occurrence estimate.
 - Although the two rounds differ somewhat (for population-exposed to concentrations greater than the HRL), the differences are relatively small (approximately a quarter million), and the maximum estimate still shows a very low occurrence. The lower of the two rounds represents the more recent data.

Preliminary regulatory determination

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- The Agency has made the preliminary determination not to regulate hexachlorobutadiene with an NPDWR because the contaminant does not occur with a frequency, or at levels, of public health concern. Monitoring data indicate that hexachlorobutadiene is infrequently detected in public water supplies. In addition to the fact that these detections are low, it is important to note that when hexachlorobutadiene is detected, it very rarely exceeds the HRL or a value of one-half the HRL.

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CCL Regulatory Determination Information Sheet *Manganese*

Background

- Essential nutrient, occurs naturally at low levels in soil, water, and food
- Variety of uses: production of steel, batteries, matches, animal feed, ceramics and nutritional supplements.

Adverse health effects

- Manganese is needed for normal growth and function; however, several diseases are associated with both deficiencies and excess intake of manganese.
- Major source of manganese intake in humans (with the exception of possible occupational exposure) is dietary ingestion; however, manganese is not considered to be very toxic when ingested with food, and reports of adverse effects are rare.
- Several reports of toxicity to humans exposed to manganese by *inhalation* which can lead to neurological symptoms (e.g., tremor, gait disorders, etc.). Much less is known about oral intake of manganese.
- EPA used only the best available peer reviewed data and analyses to characterize health effects. Based on this characterization, the Agency estimated a health-related benchmark, or Health Reference Level¹ (HRL = 300 $\mu\text{g/L}$), against which to evaluate the occurrence data.

Occurrence and exposure

- Monitored under the NIRS study³.
- EPA estimated the number of PWSs with detections $>1/2\text{HRL}$ and $>\text{HRL}$; the population served at these bench-mark values; and the geographic distribution using a large number of State occurrence data that broadly reflect national coverage.
 - Detections $>1/2\text{HRL}$. 6.1% of the reporting ground water PWSs had detections $>1/2\text{HRL}$ (60 out of 989), affecting about 4.6% of the population served (68,200 out of 1.5 million).
 - Detections $>\text{HRL}$. 3.2% of the reporting ground water PWSs with detections $>\text{HRL}$ (32 out of 989) affecting 2.6% of the population served (39,000 out of 1.5 million).

Preliminary regulatory determination

- The Agency has made the preliminary determination not to regulate manganese with a NPDWR because it is generally not considered to be very toxic when ingested with the diet and since drinking water accounts for a relatively small proportion of manganese intake. Thus, regulation would not present a meaningful opportunity for health risk reduction for persons served by PWSs.

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CCL Regulatory Determination Information Sheet *Metribuzin*

Background

- Herbicide, applications primarily targeted to soybeans, potatoes, alfalfa, and sugar cane.
- Geographic distribution of use reflects the distribution of these crops across the U.S.

Adverse health effects

- Evidence is inadequate to classify as a human carcinogen.
- For non-carcinogenic effects, the thyroid and liver are the most sensitive organs (impacting organ weight, serum levels, and enzyme activity).
- EPA used only the best available peer reviewed data and analyses to characterize health effects. Based on this characterization, the Agency estimated a health-related benchmark, or Health Reference Level¹ (HRL = 91 $\mu\text{g/L}$), against which to evaluate the occurrence data.

Occurrence and Exposure

- Monitored under the Agency's Unregulated Contaminant Monitoring program² from 1993-1999.
- EPA estimated the number of PWSs with detections $>1/2\text{HRL}$ and $>\text{HRL}$; the population served at these bench-mark values; and the geographic distribution using a large number of State occurrence data that broadly reflect national coverage.
 - Detections $>1/2\text{HRL}$ or $>\text{HRL}$. No PWSs had a detections $>1/2\text{HRL}$ or $>\text{HRL}$.

Preliminary regulatory determination

- The Agency has made the preliminary determination not to regulate metribuzin with a NPDWR because it does not occur with a frequency, or at levels, of public health concern.

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CCL Regulatory Determination Information Sheet *Naphthalene*

Background

- Naturally present in fossil fuels and is formed when wood or tobacco are burned.
- Used in the manufacture of plastics, dyes, solvents, and other chemicals.
- Crystalline naphthalene is used as a moth repellent and as a solid block deodorizer for diaper pails and toilets.

Adverse health effects

- Classified as a possible human carcinogen, *via inhalation*.
- Effects on the liver and eye (cataracts) after chronic exposure.
- High doses cause break down of the red blood cells.
- EPA used only the best available peer reviewed data and analyses to characterize health effects. Based on this characterization, the Agency estimated a health-related benchmark, or Health Reference Level¹ (HRL = 140 $\mu\text{g/L}$), against which to evaluate the occurrence data.

Occurrence and exposure

- The major source of human exposure to naphthalene is through moth-balls through either breathing the vapors or handling.
- People also may be exposed by breathing tobacco smoke and air near industries that produce naphthalene.
- Usually naphthalene is not found in water because it evaporates or biodegrades quickly.
- Monitored under the Agency's Unregulated Contaminant Monitoring program² from 1988-1992 ("Round 1") and 1993-1999 ("Round 2").
- EPA estimated the number of PWSs with detections $>1/2\text{HRL}$ and $>\text{HRL}$; the population served at these bench-mark values; and the geographic distribution using a large number of State occurrence data that broadly reflect national coverage.
 - Round 1 detections $>1/2\text{HRL}$ and $>\text{HRL}$. 0.01% of the reporting PWSs (1 out of 13,452) had detections at both $>1/2\text{HRL}$ and $>\text{HRL}$, affecting 0.007% of the population served (5,400 out of 77.2 million).
 - Round 2 detections $>1/2\text{HRL}$ and $>\text{HRL}$. 0.01% of the reporting PWSs had detections $>1/2\text{HRL}$ (2 out of 22,923), affecting 0.002% of the population served (1,300 out of 67.5 million). No PWSs had detections $>\text{HRL}$.

Preliminary regulatory determination

- The Agency has made the preliminary determination not to regulate naphthalene with an NPDWR because it is not known to occur in public water systems at levels of public health

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concern. Monitoring data indicate that naphthalene is infrequently detected in public water supplies. When naphthalene is detected, it very rarely exceeds the HRL or a value of one-half of the HRL.

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CCL Regulatory Determination Information Sheet *Sodium*

Background

- Essential nutrient, naturally occurring element
- Used in de-icing roads, water treatment chemicals, domestic water softeners

Adverse health effects

- A large body of evidence suggests that excessive sodium intake may contribute to age-related increases in blood pressure (hypertension). High blood pressure is a multi-factorial disorder with dietary sodium as one of a number of factors influencing its incidence.
- EPA used only the best available peer reviewed data and analyses to characterize health effects. Based on this characterization, the Agency estimated a health-related benchmark value based on dietary intake because of the lack of suitable dose-response data. A benchmark value of 120,000 $\mu\text{g/L}$ was used to evaluate the occurrence data.

Occurrence and exposure

- Food is the main source of exposure, primarily in the form of sodium chloride (table salt).
- Discretionary sodium intake is variable and can be quite large. The FDA has found that most American adults tend to eat between 4,000 and 6,000 mg/day.
- Sodium-restricted diets range from below 1,000 to 3,000 mg/day.
- Monitored under the NIRS study³.
- EPA estimated the number of PWSs with detections $>1/2$ benchmark value and $>$ benchmark; the population served at these benchmark values; and the geographic distribution using a large number of State occurrence data that broadly reflect national coverage.
 - Detections $>1/2$ benchmark. 22.6% of the reporting ground water PWSs have detections $>1/2$ benchmark value (224 out of 989) affecting approximately 18.5% of the population served (274,000 out of 1.5 million people).
 - Detections $>$ benchmark. 13.2% of the reporting ground water PWSs with detections $>$ benchmark value (131 out of 989) affecting approximately 8.3% of the population served (123,000 out of 1.5 million people).

Preliminary regulatory determination

- The Agency has made the preliminary determination not to regulate sodium with an NPDWR since the amount of sodium in drinking water is not projected to cause adverse health effects and since drinking water accounts for a relatively small proportion of sodium intake. Thus, regulation would not present a meaningful opportunity for health risk reduction for persons served by PWSs.

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- This preliminary decision is based on the minor impact of the sodium in drinking water when compared to the sodium in foods.
- There are inconsistencies and uncertainties in the data on the relationship between sodium intake and cardiovascular disease for populations with normal or subnormal blood pressures. Blood pressure is greatly influenced by nutrients in the diet, lifestyle, and behavioral patterns rather than sodium itself.
- EPA intends to issue an advisory to provide guidance to communities that may be exposed to elevated concentrations of sodium chloride or other sodium salts in their drinking water. The advisory will provide appropriate cautions for individuals on low-sodium or sodium-restricted diets.

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CCL Regulatory Determination Information Sheet *Sulfate*

Background

- Present in the diet, naturally occurring element
- Used for a variety of commercial purposes
- SDWA requires the following:
 - That EPA make a determination whether to regulate sulfate; and
 - EPA and the CDC to conduct a study to establish a dose-response relationship for adverse effects of sulfate, including the health effects that may be experienced by sensitive subpopulations (i.e., infants and travelers).

Adverse health effects

- Laxative effect following high acute exposures (>500 mg/L)
- Sulfate Study
 - In January of 1999, EPA and the CDC completed the study required by SDWA.
 - Investigators were unable to study infants because they could not identify enough exposed individuals from which to draw a study population.
 - In experimental trials with adult volunteers representing a transient population, the investigators did not find an association between acute exposure to sodium sulfate in tap water and reports of diarrhea.
- Sulfate Workshop
 - As a supplement to the Sulfate Study, the CDC, in coordination with EPA, convened an expert workshop, open to the public, in September of 1998.
 - Expert scientists reviewed the literature and the Sulfate Study results and favored a health advisory for sulfate-containing drinking water levels greater than 500 mg/L.
 - The most sensitive endpoint was considered to be diarrhea.
- EPA adopted the recommendation by experts at the Sulfate Workshop of 500 mg/L as a health-related benchmark, or Health Reference Level¹ (HRL), against which to evaluate the occurrence data.

Occurrence and exposure

- Monitored under the Agency's Unregulated Contaminant Monitoring program² from 1993-1999.
- EPA estimated the number of PWSs with detections >½HRL and >HRL; the population served at these bench-mark values; and the geographic distribution using a large number of State occurrence data that broadly reflect national coverage.
 - Detections >½HRL. 5% of the reporting PWSs had detections >½HRL (820 out of 16,495 PWSs), affecting about 10.2% of the population served (5.1 million out of 50.4

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million people).

- Detections >HRL. 1.8% of the reporting PWSs had detections >HRL (300 out of 16,495 PWSs), affecting about 0.9% of the population served (448,300 out of 50.4 million people).

Preliminary Regulatory Determination

- The Agency has made the preliminary determination not to regulate sulfate with an NPDWR since regulation would not present a meaningful opportunity for health risk reduction for persons served by public drinking water systems.
- This preliminary decision is based on the weight of evidence suggesting that the risk of adverse health effects to the general population is limited and acute (a short duration laxative-related response) and occurs at high drinking water concentrations (>500 mg/L, and in many cases >1,000 mg/L).
- In addition, either people develop a tolerance for high concentrations of sulfate in drinking water, or they decrease the amount of the water they drink at one time, most likely because of the taste of the water (the taste threshold is 250 mg/L).
- EPA intends to issue an advisory to provide guidance to communities that may be exposed to drinking water contaminated with high sulfate concentrations.

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Foot notes

¹For hexachlorobutadiene, manganese, metribuzin and naphthalene EPA derived a health-related benchmark, or “HRL”, against which to evaluate the occurrence data using the RfD approach as follows:
$$\text{HRL} = (\text{RfD} \times \text{BW}) / \text{DW} \times \text{RSC}.$$

Where:

RfD = Reference Dose

BW = Body weight for and adult, assumed to be 70 kg

DW = Drinking water consumption, assumed to be 2 L/day

RSC = The relative source contribution, or the level of exposure believed to result from drinking water when compared to other sources (e.g., air), and is assumed to be 20% for the HRL unless noted otherwise.

The HRL’s for sulfate and sodium are unique to each contaminant. The available data do not support the derivation of an RfD for sulfate. However, 500 mg/L is a concentration at which adverse effects did not occur in any of the reported studies. This value was used as the HRL.

The value used to evaluate the occurrence data is not designated as an HRL because of the lack of suitable dose-response data and the considerable controversy regarding the role of sodium in the etiology of hypertension. Instead a benchmark value is used. The benchmark for sodium was derived from the recommended daily dietary intake (2.4 g/day) as dissolved in 2 liters of water (1.2 g/L). It is important to note that the recommended intake is not related directly to dose-response information and is lower than most estimates of the present average daily intake of the U.S. population. A RSC of 10% was applied in recognition that foods and discretionary use of table salt are the major source of sodium exposure. This results in a benchmark value of 120 mg/L, assuming 2 liters of water per day (i.e., $2,400 \text{ mg/day} / 2\text{L} \times 10\% = 120 \text{ mg/L}$).

²Occurrence data for most of the regulatory determination priority contaminants (aldrin, dieldrin, hexachlorobutadiene, metribuzin, naphthalene, and sulfate) are from the monitoring results (State finished drinking water occurrence data) under the Agency’s Unregulated Contaminant Monitoring (UCM) program. These data form part of the Agency’s basis for its estimates of national occurrence. The UCM program was initiated in 1987 to fulfill a SDWA requirement of the 1986 amendments that PWSs [all non-purchased community water systems (CWSs) and non-purchased non-transient non-community water systems (NTNCWS)] monitor for specified “unregulated” contaminants to gather scientific information on their occurrence for future regulatory decision making purposes.

The UCM program was implemented in two phases, or “rounds.” The first round of UCM monitoring began in 1987, and the second in 1993. EPA reviewed, edited and filtered the data to meet various data quality objectives for the purposes of this analysis. Only data meeting the quality objectives described below were used.

Round 1 consists of data from 24 States with approximately 3.3 million analytical records from approximately 22,000 PWSs. Round 2 of data from 20 States with approximately 3.7 million records from slightly more than 27,000 PWSs. The actual number of systems and records varies for each contaminant according to the number of reported records for a particular contaminant.

An additional EPA study conducted in the mid-1980s, the National Inorganic and Radionuclide Survey (NIRS), provides a statistically representative sample of the national occurrence of many regulated and unregulated inorganic contaminants in ground water CWSs.

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³An additional EPA study conducted in the mid-1980s, the National Inorganic and Radionuclide Survey (NIRS), provides a statistically representative sample of the national occurrence of many regulated and unregulated inorganic contaminants in ground water CWSs.

The NIRS database includes manganese and sodium and provides contaminant occurrence data from 989 community water systems served by ground water. The NIRS does *not* include surface water systems. The selection of CWSs included in NIRS was designed so that the contaminant occurrence results are statistically representative of national occurrence at CWSs using ground water sources (the survey was focused on ground water systems, in part, because ground water has a higher occurrence and concentrations of naturally occurring IOCs). Most of the NIRS data are from smaller systems (based on population served) and each of the 989 statistically randomly selected CWSs was sampled at a single time between 1984 and 1986.

The NIRS data were collected from ground water CWSs in 49 States. Data were not available for the State of Hawaii. NIRS data were designed to be stratified based on system size (population served by the system), and uniform analytical detection limits were employed.